confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 11, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy*.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–25035 Filed 11–10–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Malnutrition in Hospitalized Adults

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Malnutrition in Hospitalized Adults,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before December 14, 2020.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Malnutrition in Hospitalized Adults. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Malnutrition in Hospitalized Adults,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/malnutrition-hospitalized-adults/protocol*.

This is to notify the public that the EPC Program would find the following information on *Malnutrition in Hospitalized Adults* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

Key Question 1. What is the association between malnutrition and clinical outcomes among hospitalized patients?

a. How do outcomes vary depending on measures or tools used to detect malnutrition?

b. Are patient-related risk factors, such as increased age or certain pre-existing health conditions, associated with poorer clinical outcomes?

Key Question 2. What is the effectiveness of screening or diagnostic assessment for malnutrition among hospitalized adults?

a. In studies that report on clinical outcomes, what is the diagnostic accuracy of screening or diagnostic assessment for malnutrition?

b. In studies that report on clinical outcomes, what is the effectiveness of screening or diagnostic assessment on measures of nutrition (nutritional stores)?

c. What is the impact of screening or diagnostic assessment on clinical outcomes?

Key Question 3. Among patients diagnosed with malnutrition, what is the effectiveness of hospital-initiated interventions used to treat malnutrition on clinical outcomes?

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)

Category	Definition
Population	Key Question 1 and 2: Hospitalized adults aged 18 years or older (see Methods section for exceptions). Key Question 1b subgroups include adults with no risk of malnutrition, adults with risk of malnutrition, and adults with baseline malnutrition. Risk factors of interest to this report include: • Older patients (>65 years) • Racial and ethnic minorities • Low income (*e.g.* Medicaid beneficiaries) • Patients with malignancy • Patients with gastrointestinal disease and subsequent malabsorption, including ulcerative colitis and Crohn's disease • Patients with chronic liver disease • Patients with stroke • Patients with chronic kidney disease • Patients with dementia • Patients with critical illness • Sepsis/infection Key Question 3: Adults diagnosed with protein-energy malnutrition.
Interventions/Exposures	Key Question 1: Positive screening for nutrition risk and/or diagnosis of malnutrition vs no malnutrition. Key Question 2: Malnutrition screening and diagnostic assessment tools (utilized within the U.S., Australia, New Zealand, Canada, and Europe). Examples of tools of interest include: *Screening*: • Malnutrition Screening Tool (MST) • Malnutrition Universal Screening Tool (MUST) • Nutritional Risk Index (NRI) • Nutrition Risk in Critically Ill (NUTRIC) score *Diagnostic Assessment*: • Subjective Global Assessment (SGA) • Patient Generated Subjective Global Assessment (PS–SGA) • Mini Nutritional Assessment (MNA) • AND (Academy of Nutrition and Dietetics)–ASPEN (American Society for Parenteral and Enteral Nutrition) Malnutrition Consensus Criteria (MCC) • Global Leadership Initiative on Malnutrition (GLIM) Key Question 3: Hospital-initiated malnutrition interventions. Examples of interventions include: • Parenteral nutrition • Enteral nutrition • Oral nutrition supplements • Nutrition team consultation, includes dietitian counseling • Pharmacologic interventions
Comparators	Key Question 1: Hospitalized patients without malnutrition, or direct comparisons of different definitions of malnutrition. Key Questions 2: Radiographic imaging or SGA will be used as the reference standard. Key Question 3: Usual care or another hospital-initiated malnutrition-related intervention.
Outcomes	*Clinical Outcomes (All Key Questions)*: • Mortality (inpatient and 30-day) • Length of stay • 30-day readmission • Quality of life • Functional status, includes gate speed, Karnofsky Index, handgrip strength, days on ventilator • Activities of daily • Hospital Acquired Condition (HAC) • Wound healing • Discharge disposition *Intermediate Outcomes (KQ 2)*: Diagnostic accuracy outcomes: • Sensitivity • Specificity • Predictive value • Area under the curve *Intermediate Outcomes (KQ 2 or KQ 3)*: Nutrition Stores: Direct measures of nutrition status (nutrition stores) during and post hospitalization. Examples include: • Cross-sectional areas for lumbar skeletal muscle and adipose tissue • Skeletal Muscle Index

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)—Continued

Category	Definition
	• Regional or total fat mass and muscle mass assessed using validated gold standard methods, such as body composition measures derived through Computed Tomography (CT) scans, Dual X-ray Absorptiometry (DXA), and Magnetic Resonance Imaging (MRI)
Timing	Up to 30 days post-discharge
Setting	Acute care hospitalizations

Dated: November 5, 2020.

Marquita N. Cullom,

Associate Director.

[FR Doc. 2020–24968 Filed 11–10–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8076–N]

RIN 0938–AU16

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2021. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2021, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2021 are $291.00 for aged enrollees and $349.90 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2021 is $148.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus the $3.00 repayment amount required under current law. (The 2020 standard premium rate was $144.60, which included the $3.00 repayment amount.) The Part B deductible for 2021 is $203.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, he or she will have to pay a total monthly premium of about 35, 50, 65, 80 or 85 percent of the total cost of Part B coverage plus a repayment amount of $4.20, $6.00, $7.80, $9.60 or $10.20, respectively.

DATES: The premium and related amounts announced in this notice are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part of the costs for physicians' services; outpatient hospital services; certain home health services; services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities; and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens and to aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

The Part B deductible to be paid by enrollees is also announced. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110, section 629 of the MMA (amending section 1833(b) of the Act) required that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2021 Part B deductible is calculated by multiplying the 2020 deductible by the ratio of the 2021 aged actuarial rate to the 2020 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that the two groups pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal-year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II Social Security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of